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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/552,892

11/26/2007

Antti Haapalinna

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EXAMINER

RAO, SAVITHA M

ART UNIT

PAPER NUMBER

1614

MAIL DATE

DELIVERY MODE

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PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/552,892	Applicant(s) HAAPALINNA ET AL.	
	Examiner SAVITHA RAO	Art Unit 1614	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 08/12/2009.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-6 is/are pending in the application.
- 4a) Of the above claim(s) 3-6 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1 and 2 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Claims 1-2 are pending.

Receipt and consideration of Applicants' amended claim set and remarks/arguments filed on August 12th 2009 is acknowledged. Claim 1 is amended and claim 7 is canceled. Claims 3-6 are withdrawn from consideration as being drawn towards nonelected specie.

Applicants' arguments, filed 08/12/2009, have been fully considered but they are not deemed to be persuasive. Rejections and/or objections not reiterated from previous office actions are hereby withdrawn. The following rejections and/or objections are either reiterated or newly applied. They constitute the complete set presently being applied to the instant application.

Claim Rejections - 35 USC § 103

**New grounds of rejection necessitated by the amended claims filed on
08/12/2009**

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

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The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 1-2 are rejected under 35 U.S.C. 103(a) as being unpatentable over Puurunen et al (Neuropharmacology 40 (2001) 597-606 already of record) in view of Ginsberg et al (Stroke, 1989; 20, pages 1627-1642) as evidenced by Leker et al (Brain Research Reviews, 42, 2003, pages 187-203)

Puurunen et al. discloses that systemic administration of atipamezole facilitates recovery following transient focal cerebral ischemia in rats (abstract) Puurunen et al. discloses that atipamezole rapidly penetrates the brain and increases the release of central noradrenaline. Puurunen et al. Also discloses that atipamezole is a potent

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alpha2-adrenoceptor antagonist with a high alpha2/alpha1 selectivity ratio with negligible affinity for other receptors such as 5-HT and imidazoline receptors (page 598, left col., 2nd paragraph). Puurunen et al. discloses brain ischemic induction in rats and treatment of these rats with atipamezole hydrochloride in sterile water administered once a day (1 mg/kg subcutaneously), beginning on day 2 of the ischemic induction and continuing for 10 days (page .598, methods, sections 2.1 and 2.2). Puurunen et al. discloses that atipamezole is well –tolerated over a wide range of doses and that atipamezole improved behavioral performance of ischemic rats and accordingly provides a promising pharmaceutical approach to facilitate the recovery process following cerebral ischemia (page 604, right col., last paragraph).

Puurunen does not teach the administration of the drug to human patient at risk of developing epilepsy.

However, animal testing in biomedical research is used as a reflection of the final outcome in humans. As disclosed by Ginsberg et al the use of physiologically regulated, reproducible animal models is crucial to the study of ischemic brain injury- both the mechanisms governing its occurrence and potential therapeutic strategies (abstract), Ginsberg additionally teaches that rodent species are readily available at low cost and are widely employed for this purpose (abstract). In addition Ginsberg teaches that Rodents have close resemblance of the cerebrovasuclar anatomy an physiology to that of higher species (page 1627, right col., 1st paragraph). Accordingly, it would have been obvious to an ordinarily skilled artisan to extrapolate the results obtained by Puurunen et al which clearly recites the beneficial effects of atipamezole as a promising

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pharmaceutical approach to facilitate the recovery process following cerebral ischemia. in rats to that of mammals and specifically humans and as such develop a method of treating human patients with brain ischemia with atipamezole. An ordinarily skilled artisan will be imbued with at least a reasonable expectation of success that such a method would provide an alternative and potentially better therapeutic treatment procedure for brain ischemia.

Leker et al is used here as evidentiary document to demonstrate that cerebral ischemia leads to epileptic attack. Leker et al teaches that epileptic seizures may be the result of cerebral ischemia and may also cause brain damage and additionally, suggests that the pathological mechanisms leading to epileptic seizures are identical to those involved in cerebral ischemia (page 188, left column). Leker additionally teaches that experimental models using focal ischemia, usually obtained by occlusion of the middle cerebral artery are representative of stroke pathophysiology (page 190, right col. Last paragraph to page 191, left col. 1st paragraph). As such an ischemic patient would essentially be at risk of epileptic seizures. Therefore, when a patient with brain ischemia is treated with atipamezole, the compound will inherently inhibit the development of epilepsy upon administration. It is noted that "Products of identical chemical composition can not have mutually exclusive properties." A chemical composition and its properties are inseparable. Therefore, if the prior art teaches the identical chemical structure, the properties applicant discloses and/or claims are necessarily present. In re Spada, 911 F.2d 705, 709, 15 USPQ2d 1655, 1658 (Fed. Cir. 1990). As such the instantly claimed mechanistic functions of the compounds to inhibit the development of

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epilepsy would be present in the identical compound being administered to human suffering from brain ischemia as taught by Puurunen et al. and Ginsberg et al. and would therefore elicit these effects whenever it is administered.

Response to applicant's arguments filed on 08/12/2009:

In light of the new grounds of rejection above, the arguments submitted on 08/12/2009 which was for the previously submitted rejection is moot.

Conclusion

Claims 1 and 2 are rejected. No claims are allowed

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

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Any inquiry concerning this communication or earlier communications from the examiner should be directed to SAVITHA RAO whose telephone number is (571)270-5315. The examiner can normally be reached on Mon-Fri 7.00 am to 4.00 pm..

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ardin Marschel can be reached on 571-272-0718. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/SAVITHA RAO/
Examiner, Art Unit 1614

/Ardin Marschel/
Supervisory Patent Examiner, Art Unit 1614